EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

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IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

MDL NO: 16-2738 (FLW)(LHG)

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THIS DOCUMENT RELATES TO ALL CASES

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DEPOSITION UNDER ORAL EXAMINATION OF

SARAH E. KANE, M.D.

January 25, 2019, 9:19 a.m.

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REPORTED BY: JANET M. SAMBATARO, RMR, CRR, CLR

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separating out.

I've looked at the talcum powder product that women use on their perineum, what they bought off the shelf. I haven't looked at pharmaceutical-grade -- let me correct that -- pleurodesis talc, for example. I have not looked at pleurodesis talc and ovarian cancer. I have not looked at any literature specifically on that. It's been the talcum powder products that women are buying off the shelf and using on their perineum.

Q. So if I told you that Johnson's baby powder starts out as pharmaceutical-grade talc and that, beyond that, fragrance is added, would it be the fragrance that you're taking issue with that you believe is causally associated with the development of ovarian cancer?

A. Again, I -- it's whatever is in that bottle. It could be platy talc, fibrous talc, asbestos, heavy metals, fragrance. It -- to me, it's the product, whatever the product is that they are using.

Q. And you have done a biologic plausibility analysis for fragrances, for metals, for asbestos, for fibrous talc, and for platy

talc --

A. So --

Q. -- each one of those constituents?

A. So I have looked at evidence -- so Dr. Crowley's report, I mentioned. I've looked at Dr. Longo's report. I've looked at Hopkins and the Pier charts from their depositions. I'm aware of evidence that these heavy metals and fragrances and asbestos are in there.

However, I haven't done -- what I know, I looked at the -- I've looked at some literature and I've looked at the IARC categorization of the heavy metals. I've looked at Dr. Crowley's report and I've done an extensive look at asbestos and ovarian cancer.

But, ultimately, those are just pieces of biological plausibility. What I'm mainly -- what I am opining about is the ultimate product. And, again, it can be platy talc, it can be fibrous talc, it can be asbestos, it can be heavy metals.

It's pieces of information that strengthen the plausibility. We know that asbestos causes ovarian cancer, that certain heavy metals are carcinogens, which the IARC categorized them as. So it's just -- it's just additional pieces of

information that strengthen the biological plausibility arm of it.

Q. Doctor, how do you arrive at a causation conclusion without a well-defined agent of exposure?

MR. ROTMAN: Objection.

Q. Do you understand what I'm asking you? How do you arrive at your causation and conclusion when you're not sure what it is about the talcum powder products that's actually biologically relevant?

A. Well, I think -- well, strike that.

The epi studies are looking at the product that the women are using. So that is the agent. It's the -- it's the total product. That is the agent.

So when you're looking through -- let me just -- so let's keep in mind that we're looking at that product.

And then if you go through my Bradford Hill analysis, you look at strength of association. And, overall, there's a consistent relative risk that's between 1 and 2. I would say it's, across studies, averaging 1.3 to 1.4 relative risk, and that's consistent across studies. That's the

an answer about the epi studies are looking at the product that the women are using, and you were talking about strength of association and then you said, "And that's consistent across studies. That's the consistency piece of it," and then you were interrupted.

So were you done with your answer to that earlier question?

THE WITNESS: I can continue, because I think it's important.

I mean, I was -- my general causation opinion, the methodology I used was to answer the question: Does perineal application of talcum powder products, the, you know, baby powder product that you buy off the shelf, does that cause ovarian cancer? So it's whatever is in that bottle.

So with the methodology that I used, looking at the epi data, but also considering the Bradford Hill criteria -- which, you know, looking for specificity is another one. So most of the studies showed a stronger -- a strong association with serous ovarian cancer, but it was basically associated with epithelial ovarian cancer, so all groups of epithelial ovarian

cancer. It was pretty specific, the epi data, for that type of ovarian cancer.

Temporality. If you look at that, I mean, the case-control studies are retrospective reviews, so we know that they were using talc before their diagnosis of ovarian cancer.

Biological gradient. For those studies that looked at a biological gradient, there was an evident -- there was evidence of a dose-response, not all of the times statistically significant, but the trend -- you can see a trend of a dose-response across studies.

And then we get into the plausibility piece, which you've been discussing mostly so far in this deposition, which has to do with the plausible mechanism of talcum powder -- what I'm thinking of, talcum powder products -- whatever is in that bottle was what I'm looking at -- talcum powder products causing -- the plausibility of it causing a chronic inflammatory response, leading to ovarian cancer. We've been discussing that quite a bit today.

And then coherence. So I can refer again to my report. Coherence, in this context, means coherence between epidemiologic and

generally accepted knowledge of the disease in question.

So we know that particles can reach the ovary. We know that talc can cause chronic inflammation. We know that chronic inflammation is associated with certain types of cancer. We know that certain types of ovarian cancer have shown association with chronic inflammatory conditions.

So, again, going through all this is experiment and analogy, experiment with the animal studies and the in vitro studies. And analogy, I used the example of asbestos, because even though asbestos is -- you know, asbestos is chemically similar, you can have asbestos fibers and talc fibers, but it's a similar mineral chemically, and we know that that is a carcinogen. So that's part of the analogy.

But, again, it's the whole picture. I mean, you look at the -- all of this data following my methodology and you apply the Bradford Hill criteria guidelines -- the Bradford Hill guidelines. And, looking at all that, my professional judgment is that the talcum powder products can cause ovarian cancer.

little too wide a net. I think science is always evolving and there's always the possibility of an unknown cause of a certain type of cancer.

MS. AHERN: Objection. Nonresponsive.

Q. My question was just: Can carcinogens be organ specific?

A. And I feel like I answered that fairly.

Q. Do you know of carcinogens that are organ specific?

A. I know -- for example, we know that H. Pylori causes increased risk of gastric cancer, but not oral or esophageal cancer.

We know that HPV infection can cause cervical cancer, anal cancer, certain types of squamous cell carcinomas of the oropharyngeal system, but not, you know, of the endometrium, for example.

So we know that certain things cause certain cancers and aren't -- haven't been associated with other types of cancers. But to cast that wide a net, to say that a carcinogen is only going to cause one type of cancer or this cancer is caused only by this carcinogen, I think that's too wide a net, because I feel like research is constantly evolving. We're constantly learning

of new causal factors in cancer.

Q. Do you think that dose is an important consideration when you're looking at the toxicologic effects of an agent on a tissue?

A. I think it is a piece of information. I'm looking at my biological gradient portion of my report, and I said in my report that it was an important factor in my analysis because it does add information to the overall causality.

Q. Are there agents that can be toxic at certain levels and not toxic at other levels?

A. There are certainly agents that are more toxic with increased exposure and increased duration. We don't know all of the thresholds for carcinogenicity of all carcinogens.

Q. As part of the biologic plausibility analysis that you would do on a particular agent, would that take into consideration the relative levels of exposure that a person would have to that agent?

A. Well, dose-response -- I -- I'm taking it -- your question -- can you rephrase the question? I'm sorry. I just want to make sure I'm answering it accurately.

Q. To determine whether it's biologically

biology and inflammation, are you?

A. I am not currently participating in a study of oxidative stress or redox biology.

Q. You don't have any funding related to oxidative stress and inflammation, do you?

A. No, I do not.

Q. Have you ever applied for any funding in that area?

A. No. I have not.

Q. Have you ever authored a systematic review of the literature on oxidative stress and inflammation?

A. Oxidative stress and inflammation, no. I don't believe I have.

Q. Have you ever authored a systematic review of the literature on oxidative stress and cancer?

A. No. I have not authored a systematic review on that.

Q. Okay. Doctor, moving on to inflammation and ovarian cancer.

Generally, on inflammation, can you cite to a published experiment that was conducted in animals in vivo that establishes a role of any particular inflammatory cell or cytokine or